JUL 11 2008

510(K) SUMMARY

CardioSen'C

510(k) Number K 080047

Applicant's Name: SHL Telemedicine International Ltd.
90 Igal Alon St.
Tel Aviv 67891
ISRAEL
Tel (972)3-561-2212
Fax (972)3-624-2414

Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: CardioSen'C

Classification: **Name**: Telephone electrocardiograph transmitter and receiver
Product Code: DXH
Regulation No: 21 CFR 870.2920
Class: II
Panel: Cardiovascular

Device Description: The CardioSen'C is a personal, battery powered, hand-held personal ECG transmitter, enabling an individual to immediately transmit a 12-lead ECG and a rhythm strip from a remote location, to a physician's office, hospital or monitoring center.

The ECG data can be transmitted in real time via two communication methods. The CardioSen'C produces an ECG frequency modulated acoustical tone that can be coupled with and transmitted by a standard or a cellular telephone. The ECG data can also be transmitted digitally through the cellular network. Either one of these two transmissions methods permits the transfer of a 12-lead ECG and rhythm strip to the medical professional capable of interpreting the data.

Intended Use Statement:

The CardioSen'C device is intended to condition an electrocardiographic signal so that it can be transmitted acoustically via telephone and/or digitally over cellular network to a remote location. The CardioSen'C device is designed to be used by a patient to transmit a 12 lead ECG and rhythm strip in real-time to a physician's office, hospital or other medical receiving center.

Predicate Devices:

The CardioSen'C is substantially equivalent to the following predicate devices:

- CardioBeeper ® CB 12/12, 12 Lead Personal ECG Transmitter, cleared under K002310;
- River – 1, ECG Event Recorder and Transmitter, cleared under K063609.

Performance Data:

The CardioSen'C device has been tested according to various standards and guidance documents, such as ANSI/AAMI EC11-1991 (Diagnostic Electrocardiographic Devices), IEC 60601-2-25 (1993) +A1:1999 requirements for the safety of electrocardiographs, etc. Further IVD study has shown that the system meets its design specifications and is safe and effective for its intended use.

Conclusions:

The CardioSen'C device has the same intended use and is capable of transmitting the electrocardiographic signal acoustically via customary telephones as the CardioBeeper® CB 12/12. Further, the CardioSen'C can transmit digitally over cellular network to a remote location as the River -1 device. The results of tests studies and analyses performed with the CardioSen'C device demonstrate that the CardioSen'C device is as safe and effective as its predicate devices without raising any new safety and\or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2008

SHL TeleMedicine International LTD
c/o Qsite
Mr. Yoram Levy
31 Haavoda St.
Binyamina, 30500
ISRAEL

Re: K080047
CardioSens'C
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DXH
Dated: June 22, 2008
Received: June 27, 2008

Dear Mr. Levy:

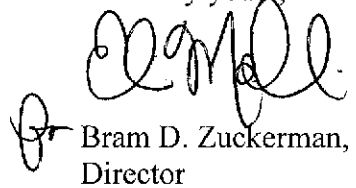
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SHL
TeleMedicine International Ltd.

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K080047

Device Name: CardioSen'C

Indications for Use: The CardioSen'C device is intended to condition an electrocardiographic signal so that it can be transmitted acoustically via telephone and/or digitally over cellular network to a remote location. The CardioSen'C device is designed to be used by a patient to transmit a 12 lead ECG and rhythm strip in real-time to a physician's office, hospital or other medical receiving center.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Cardiovascular, Respiratory and Neurological Devices
510(k) Number

(Division Sign-Off)
Division of Cardiovascular Devices